Message

From: D'Amico, Louis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=78A91F83C4414910BE286EFE02004DBC-D'AMICO, LOUIS J.]
Sent: 9/18/2018 2:16:39 PM
To: Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]
Subject: RE: Chloroprene briefing - Urgent - please comment on agenda and participants and I'll outreach starting today

Dammit…good catch. Thx.

Louis D'Amico, Ph.D.
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Office: 202-564-4605 | Mobile: Deliberative Process / Ex. 5 | email: damico.louis@epa.gov

From: Vandenberg, John
Sent: Tuesday, September 18, 2018 10:16 AM
To: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: RE: Chloroprene briefing - Urgent - please comment on agenda and participants and I'll outreach starting today

Note top line fix to **Reagan**

From: D'Amico, Louis
Sent: Tuesday, September 18, 2018 10:13 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Subject: RE: Chloroprene briefing - Urgent - please comment on agenda and participants and I'll outreach starting today

Alright. I'll throw in front of JOZ ASAP. Thx!

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From: Bahadori, Tina
Sent: Tuesday, September 18, 2018 10:11 AM
To: Thayer, Kris <thayer.kris@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Subject: RE: Chloroprene briefing - Urgent - please comment on agenda and participants and I'll outreach starting today

I'm good too.

From: Thayer, Kris
Sent: Tuesday, September 18, 2018 10:10 AM

To: D'Amico, Louis <DAmico.Louis@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: RE: Chloroprene briefing - Urgent - please comment on agenda and participants and I'll outreach starting today

No comments from me either

From: D'Amico, Louis
Sent: Tuesday, September 18, 2018 9:25 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: RE: Chloroprene briefing - Urgent - please comment on agenda and participants and I'll outreach starting today

No comments from me, I threw it into a word document to make it easier for edits (and made a couple minor edits myself along the way). See what you all think, and let me know when it's good to share with JOZ. Thx.

-Lou

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From: Vandenberg, John
Sent: Tuesday, September 18, 2018 8:24 AM
To: Thayer, Kris <thayer.kris@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: Chloroprene briefing - Urgent - please comment on agenda and participants and I'll outreach starting today
Importance: High

Here's a draft agenda including sequence, topics, proposed time slots. Jennifer can share this with Anne or others if that's best next step.

If this looks OK I'll contact key people today to get them on board (I see the "leads" on the invitation but not all staff that might be called upon e.g., Kelly Rimer, Fran Verhalan and Provi Spina).

I've developed it to have ORD (JOZ) run the meeting.

Comments please.

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Deliberative Process / Ex. 5

From: Thayer, Kris
Sent: Monday, September 17, 2018 9:02 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>
Cc: Vandenberg, John <Vandenberg.John@epa.gov>
Subject: RE: Pre-brief on chloroprene

Actually, I only just now saw the inside EPA article https://insideepa.com/daily-news/epa-agrees-industry-request-review-chloroprene-iris-analysis

Daily News

EPA Agrees To Industry Request To Review Chloroprene IRIS Analysis

September 17, 2018

Months after rejecting an industry data quality request to revise a controversial risk analysis for chloroprene, a chemical used to make synthetic rubber, EPA appears to have opened the door to reviewing the science underlying its original analysis, a move that could set a precedent for any future requests for correction (RFC).

EPA has not formally agreed to reconsider its Jan. 25 decision rejecting an RFC that Denka Performance Elastomers (DPE) filed under the Data Quality Act (DQA) to revise its 2010 Integrated Risk Information System (IRIS) assessment of the human health risks of chloroprene. The IRIS assessment has proven controversial because, when coupled with air pollution modeling, drove strict controls on the company's plant in LaPlace, LA.

But top EPA risk assessors have reached an agreement with the company's consultants to analyze and potentially advance to peer review a new physiologically-based pharmacokinetic (PBPK) model, which are

generally used to project absorption, distribution, metabolism and excretion (ADME) of synthetic or natural chemical substances in humans and other animal species, that could be used to revise the agency's controversial 2010 assessment.

"They've proposed to develop a PBPK model . . . they're in the process of developing it," an EPA source tells *Inside EPA*, explaining a July meeting on the issue between IRIS leaders and Denka's consultants at Ramboll Environ, and Louisiana Department of Environmental Quality (LDEQ) officials.

At the meeting, Denka and its consultants reiterated their concerns with the 2010 IRIS assessment, and also discussed their ongoing PBPK modeling effort.

Once peer-reviewed, the model could be used to update EPA's 2010 IRIS assessment of chloroprene, which Denka and its consultants argue contains too strict a cancer risk estimate.

The EPA source says "if the model comes in and it's of good quality," the agency will have it externally peer-reviewed.

In a July 24 letter after the meeting, Denka thanked IRIS leadership for "the opportunity to present the findings from our updated PBPK model and sensitivity analyses" and also outlined the company's understanding of its agreement with the agency.

"We are prepared to provide EPA with a working PBPK model with full documentation that will allow EPA to use the model and perform the necessary internal and external peer review. . . . We look forward to providing EPA with all the necessary support to facilitate the entire process. We were pleased to hear that EPA intends to give high priority to the PBPK model evaluation and we look forward to receiving an updated timeline for the evaluation process."

The controversy over the IRIS assessment led to a critical House science committee hearing on the IRIS program last fall, and prompted Denka to file its RFC against the IRIS assessment under the DQA. EPA denied the request last January, and Denka appealed to the agency in a request for reconsideration in July.

NATA Data

Concerns with the Denka plant originated with EPA's 2015 release of its 2011 National Air Toxics Assessment (NATA) data showing high levels near the plant of the likely carcinogen chloroprene, combined with the 2010 IRIS assessment. EPA and LDEQ are using NATA to target the plant's emissions - a novel use of the air toxics data to support specific compliance action rather than broader strategic efforts.

In its first appeal to EPA in June 2017, Denka filed the RFC along with a letter from its president and CEO, Koki Tabuchi, who formally petitioned to "withdraw and correct" what he considered errors in EPA's 2010 assessment.

The analysis classified chloroprene as a likely human carcinogen and sets an inhalation unit risk (IUR) estimate for cancer potency of 5x10^-4 per microgram per cubic meter of air (ug/m^3)^-1 when inhaled daily over a lifetime.

This IUR, together with the NATA data, is the basis for the enforcement effort to reduce the plant's emissions to 0.2 micrograms per cubic meter (ug/m^3). But Tabuchi blamed the IRIS assessment for enforcement actions from state and federal officials that he says could force the facility to close.

Tabuchi charged that EPA and LDEQ "pressed DPE to reduce emissions to achieve an extraordinarily miniscule ambient air target concentration of 0.2 ug/m^3 for chloroprene on an annual average basis . . . based on a risk assessment that applied the erroneous and scientifically unsubstantiated IUR from the 2010 IRIS" assessment.

Meanwhile, surrounding residents have sought to file a class action suit against the company, arguing that it is insufficiently protecting them from cancer risks.

EPA last January denied Denka's RFC after IRIS scientists conducted a systematic review to determine if any newly available information would justify updating the 2010 assessment. Systematic review is a structured and documented process for transparent literature review and evaluation of the information. IRIS has been developing an approach for its use over the past several years.

The IRIS staff concluded that seven new chloroprene studies evaluated "represent novel approaches to analyzing existing epidemiologic, toxicological, and toxicokinetic data available for chloroprene. However … it is the opinion of the EPA that these studies do not present sufficient evidence or provide adequate rationale for re-evaluating the entire chloroprene toxicity database."

But, the EPA source says, Denka consultants "recognized in reading the denial an opportunity to address one of the critical questions -- the ability to use a PBPK model."

The agency's denial of the RfC explains that "EPA ultimately concluded that the PBPK model available at the time of the assessment was inadequate for calculation of internal dose metrics or interspecies dosimetry extrapolations for a number of reasons," before going on to evaluate three newer studies that Denka argued in the RfC "address critical model validation issues identified at that time as a barrier to the application of a PBPK model."

But EPA instead concluded that "there are a number of serious concerns regarding the development and/or application of the PBPK models (Yang et al., 2012), including poor model optimization that resulted in underestimates of organ-specific metabolism (i.e., kidney) and unexplained inconsistencies between the internal dose metric and tumor response in male mice."

Further, when EPA sought to obtain model code for the Yang study, they were unable to provide complete, documented code, making it impossible for agency modelers to review it.

Request For Reconsideration

In its July 24 request for reconsideration, Denka continues to protest EPA's 2010 cancer risk estimate, arguing that EPA erred in concluding that epidemiological data on chloroprene supports a causal relationship between exposure to the chemical and cancer, or that it supports EPA's finding that chloroprene is a likely carcinogen.

The request also charged that EPA ignored its cancer risk assessment guidelines and its peer review panel when it selected the mouse as predictive of human response. In addition, it charged that EPA incorrectly selected mouse data as the basis for its estimate, and did not use a PBPK model in its calculations and that it failed to address criticisms about several of these decisions raised by the panel of independent experts who peer reviewed the draft.

As a result, Denka argues that its consultants "calculated that EPA overestimated the IUR by a factor of 156." In its request for reconsideration, Denka adds that "The erroneous IUR has directly harmed [DPE] as the owner and operator of the only Neoprene production facility in the United States."

The company calls itself "an environmentally proactive company and is fully committed to complying with environmental requirements." It argues that even though it is challenging the IRIS assessment, it has complied with regulatory requirements, noting that it voluntarily agreed with LDEQ to reduce emissions by about 85 percent compared to its 2014 emissions.

This has required controls costing "more than $30 million" to install and hundreds of thousands per year in operating costs. But despite those costs and reductions, Denka will still not be able to achieve the 0.2 ug/m3 target."

Denka argues that EPA should not have denied its earlier RFC, because if EPA had "considered DPE's RFC on the scientific merits, EPA would have recognized that the 2010 Review does not represent the best available science, methods, or interpretations. EPA would have recognized that the epidemiological evidence does not provide any credible evidence of a link between chloroprene exposure in workers and increased risk of lung or liver (or any other) cancer mortality. EPA would also have recognized that EPA's IUR, based on the female B6C3F1 mouse, grossly overestimates potential human risks."

The company adds that it also disagrees with EPA's "dismissal of two key new studies that support the application of a PBPK model to correct the chloroprene IUR, (Yang et al. (2012) and Allen et al. (2014)). However . . . DPE's consultants have developed a PBPK model that DPE believes addresses EPA's concerns about currently available PBPK models for chloroprene."

The agency source calls the situation "a real effort by both the company and EPA to utilize the best available science. . . . They've committed substantial efforts to reduce emissions . . . even as they're having that contractor develop this model. They haven't waited" to take pollution control measures."

Similarly, the source anticipates that EPA will work quickly to review anything that comes in, "because there is a lot of concern in the community." -- *Maria Hegstad* (mhegstad@iwpnews.com)

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From: Bahadori, Tina
Sent: Monday, September 17, 2018 5:58 PM
To: D'Amico, Louis <DAmico.Louis@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Cc: Vandenberg, John <Vandenberg.John@epa.gov>
Subject: RE: Pre-brief on chloroprene

Yes, that sounds like a good proposed plan – and it will get everyone to speak to where they are and what they are doing…not just ORD. I assume everyone saw the InsideEPA article today?

From: D'Amico, Louis
Sent: Monday, September 17, 2018 5:01 PM
To: Thayer, Kris <thayer.kris@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Vandenberg, John <Vandenberg.John@epa.gov>
Subject: RE: Pre-brief on chloroprene

So Anne is coming in specifically for this meeting. Jennifer would like to share a draft agenda as soon as possible to make sure it meets her needs. John, what you described below sounds like it would work, and Jennifer is thinking you were working something up.

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From: Thayer, Kris
Sent: Monday, September 17, 2018 3:49 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>
Cc: Vandenberg, John <Vandenberg.John@epa.gov>
Subject: Re: Pre-brief on chloroprene

Thanks Lou for the context and thanks Tina for the update

Sent from my iPhone

On Sep 17, 2018, at 3:45 PM, Bahadori, Tina <Bahadori.Tina@epa.gov> wrote:

> OK, that's fine. I checked with OEI today. The RFR is still ongoing. OEI is waiting for Betsy Shaw to accept to be on the Executive Committee.
> T>
>
> **From:** D'Amico, Louis
> **Sent:** Monday, September 17, 2018 3:38 PM
> **To:** Bahadori, Tina <Bahadori.Tina@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
> **Cc:** Thayer, Kris <thayer.kris@epa.gov>
> **Subject:** RE: Pre-brief on chloroprene
>
> Still haven't caught JOZ yet. I think the mock agenda is consistent with what the intent of the meeting is. I think the driver is that the R6 RA (Anne Isdal) will be in DC, so the timing is to coincide with her visit. 2 hours is probably too long, but It gives talking time for different parts of the agency to report out on where they are and make sure we're all on the same page with consistent talking points.
>
> I'll try and catch her at the happy hour today to confirm, but wanted to download what I've been able to pull together.
>
> -Lou
>
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>
> **From:** Bahadori, Tina
> **Sent:** Monday, September 17, 2018 11:41 AM
> **To:** D'Amico, Louis <DAmico.Louis@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
> **Cc:** Thayer, Kris <thayer.kris@epa.gov>
> **Subject:** RE: Pre-brief on chloroprene
>
> Good – see if you can find out what the driver is for the big meeting.
> T>

From: D'Amico, Louis
Sent: Monday, September 17, 2018 11:40 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: Re: Pre-brief on chloroprene

I'll try and get in with joz in a bit. I'm getting in late due to a Dr's appointment. Saw she just scheduled the meeting.

Sent from my iPhone
(Please pardon brevity and typos)

On Sep 17, 2018, at 9:12 AM, Vandenberg, John <Vandenberg.John@epa.gov> wrote:

> Lou - please let us know what is wanted - my initial sense from >month ago was a quick update, but this AA-level meeting is set up for 2 hours which seems very long.
>
> **Is the purpose to have all organizations summarize what they're doing?**

Deliberative Process / Ex. 5

> I can work on getting an agenda together once the purpose is clear.
> Thanks
> John

From: D'Amico, Louis
Sent: Friday, September 14, 2018 8:52 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Vandenberg, John <Vandenberg.John@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: Re: Pre-brief on chloroprene

I don't know that I was in the conversation where this was decided. I can explore on Monday...

Sent from my iPhone
(Please pardon brevity and typos)

On Sep 14, 2018, at 7:29 PM, Bahadori, Tina <Bahadori.Tina@epa.gov> wrote:

> I've lost track – why are we doing this cross-agency discussion on the 24th? I will let John and Kris provide an update on what is going on, but essentially, the RfR is unfolding and the team is working diligently with Exponent on the PBPK model.
>
> T.

From: D'Amico, Louis
Sent: Friday, September 14, 2018 4:06 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Subject: Pre-brief on chloroprene

Hi Tina and John,

Jennifer mentioned to me earlier today that she thought it would be good for us to have a pre-brief on where we're at with chloroprene in advance of the cross agency discussion on the 24th. I realize that means finding some time next week. Any concerns?

-Lou

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